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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/502,062

07/20/2004

Shogo Miki

81844.0027

8649

26021 7590 05/30/2007  
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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

05/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/502,062

Applicant(s)

MIKI ET AL.

Examiner

Laura A. Bouchelle

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-3, 5-7, 9, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hisamatsu et al (US 6533754) in view of Ishida (US 5879369). Hisamatsu discloses a catheter having a balloon 12, a shaft 13, and a guidewire tracking lumen 11 in the distal portion. The guidewire tracking lumen crosses the interior of the balloon and has a guidewire port 141 located less than 10 mm from the proximal end of the inflated balloon (Col. 6, lines 6-8). See Fig. 2. The shaft comprises a material such as SUS or a super elastic material such as Ni-Ti alloy (Col. 6, lines 43-48). The catheter includes a radiopaque marker 121 disposed on the interior of the balloon (Col. 4, lines 58-59). The balloon can be formed of silicone or polyurethane (Col. 7, line 57- Col. 8, line 8).
3. Claim 1 differs from Hisamatsu in calling for the balloon to have an elongation at break of 300% to 1000% and the shaft to have a bending modulus of at least 1 GPa. Ishida teaches a balloon catheter having a balloon with an elongation at break of about 500% and a bending modulus of  $2950 \text{ kg/cm}^2$  (2.35 GPa) to allow the device to have adequate strength to dilate a vessel and still be flexible enough to give satisfactory tracking capability (Col. 16, lines 36-38).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Hisamatsu to have elongation at break of about 500% and a bending modulus of  $2950 \text{ kg/cm}^2$  (2.35 GPa) as taught by Ishida so that the device has the desired characteristics.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hisamatsu in view of Ishida as applied to claim 3 above, and further in view of Cragg (US 5085635). Claim 4 differs from the teachings above in calling for the guidewire port to be closed when no guidewire is present in the lumen. Cragg teaches a catheter having a guidewire port that has a valve that is closed when there is no guidewire in the lumen to prevent discharge of fluid from the guidewire port (Col. 2, lines 9-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Hisamatsu in view of Ishida to have a guidewire port that has a valve that is closed when there is no guidewire in the lumen as taught by Cragg to prevent discharge of fluid from the guidewire port.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hisamatsu in view of Ishida as applied to claim 1 above, and further in view of Imran et al (US 5766203). Claim 8 differs from the teachings above in calling for the outer surface of the catheter to be coated. Imran teaches a catheter coated with a layer of tetrafluoroethylene (Teflon®) to allow the shaft to be inserted into the vasculature with minimum friction (Col. 5, lines 3-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device

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of Hisamatsu in view of Ishida to include a tetrafluoroethylene coating as taught by Imran so that the device can be inserted into a vessel with minimum friction.

***Response to Arguments***

6. Applicant's arguments filed 2/16/07 have been fully considered but they are not persuasive.

7. Applicant argues that the references do not teach a bending modulus of at least 1 GPa. Ishida teaches a polymer having a bending modulus of 2950 kg/cm<sup>2</sup> which is more than 1 GPa and an elongation an elongation at break of 550% (Col. 11, lines 49-50). This material is used for the base layer of a balloon catheter that is used in both the balloon and the shaft portion of the device.

8. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle  
Examiner  
Art Unit 3763



**NICHOLAS D. LUCCHESI**  
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